DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 23, 2017

B. Braun Medical, Inc.
Nancy Skocypec
Associate Director, Regulatory Affairs
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

Re: K163430
Trade/Device Name: Prontosan Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 25, 2017
Received: April 27, 2017

Dear Nancy Skocypec:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163430

Device Name
Prontosan® Wound Gel

Indications for Use *(Describe)*
OTC Use: Prontosan® Wound Gel is intended to cleanse and moisten the wound bed and for the management of minor cuts, abrasions, lacerations, and minor burns.

Professional Use: Prontosan® Wound Gel is intended to cleanse and moisten the wound bed and for the management of ulcers, 1st and 2nd degree burns, partial and full thickness wounds, and surgical incisions. It can be used during wound dressing changes to soften encrusted wound dressings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) SUMMARY

Date:	May 22, 2017
Submitter:	B. Braun Medical Inc. 901 Marcon Boulevard Allentown, PA 18109-9341 (610) 266-0500
Contact:	Nancy Skocypec
Phone:	(610) 596-2796
FAX:	(610) 266-4962
E-mail:	nancy.skocypec@bbraun.com
Trade Name:	Prontosan® Wound Gel
Common Name:	Wound Cleanser, Wound Dressing
Product Code:	FRO, Dressing, Wound, Drug
Classification:	Unclassified
Predicate Device:	Prontosan® Wound Gel, B. Braun Medical Inc., K101882
Reference Device:	Wound Gel X, B. Braun Medical Inc., K130857

INDICATIONS FOR USE

OTC Use: Prontosan Wound Gel is intended to cleanse and moisten the wound bed and for the management of minor cuts, abrasions, lacerations, and minor burns.

Professional Use: Prontosan® Wound Gel is intended to cleanse and moisten the wound bed and for the management of ulcers, 1st and 2nd degree burns, partial and full thickness wounds, and surgical incisions. It can be used during wound dressing changes to soften encrusted wound dressings.

DEVICE DESCRIPTION

Prontosan® Wound Gel is a clear, colorless and virtually odorless gel containing undecylenamidopropyl betaine, polyaminopropyl biguanide, glycerol, hydroxyethylcellulose and purified water. Prontosan Wound Gel is a nonpyrogenic solution used for wound management.

Prontosan Wound Gel will be offered in an over-the-counter (OTC) version and a professional use (Rx only) version. Prontosan Wound Gel is used to moisten the wound bed and clean the wound surface, including those that are difficult to access. Prontosan Wound Gel is aseptically

filled into a 30 mL low density polyethylene squeeze bottle with a screw cap.

SUBSTANTIAL EQUIVALENCE

The subject device and the predicate device are the same. No changes have been made to the device design, packaging, manufacturing process, indications for use or the intended use. The changes subject to this 510(k) are for labeling content only.

CONCLUSION

Prontosan™ Wound Gel for prescription and over the counter use is identical to the predicate device in formulation, manufacturing, packaging and intended use. B. Braun believes the predicate and subject devices to be substantially equivalent.